

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rachel E. Meyers and Laura A. Rudolph-Owen
Divisional Application N/A Group No.: Not Yet Assigned
of Application No.:
Filed: February 24, 2004 Examiner: Not Yet Assigned
For: 26934, A NOVEL CYTIDINE DEAMINASE-LIKE MOLECULE AND USES
THEREOF

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements;
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449);
3. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted (1-8, U-X, 14-22)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

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Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Identification of Prior Application in Which Listed Information Was Already Cited
and for Which No Copies Are Submitted or Need Be Submitted**

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application Serial No. 09/802,371, filed on March 9, 2001.

The cited references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application. However, the undersigned will provide additional copies upon request.

February 24, 2004

MILLENNIUM PHARMACEUTICALS, INC.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known			
		Application Number	N/A		
		Filing Date	February 24, 2004		
		First Named Inventor	Rachel E. Meyers, et al.		
		Group Art Unit	N/A		
		Examiner Name	N/A		
Sheet	1	of	4	Attorney Docket Number	MPI00-022PIRDVIM

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T ²
	1	Chan, et al., (1996) "Apolipoprotein B mRNA Editing Protein: A Tool for Dissecting Lipoprotein Metabolism and a Potential Therapeutic Gene for Hypercholesterolemia," Gastroenterol. 34(3):31-31.	
	2	Chang, et al., (1998) "Evolutionary Analysis of RNA Editing Enzymes," Methods Companion Methods Enzymol. 15(1):41-50.	
	3	Eliopoulos et al., (1999) "Chemoprotection Against Cytosine Nucleoside Analogs Using the Human Cytidine Deaminase Gene," Prog. Exp. Tum. Res. 36:124-142.	
	4	Smith et al., (1996) "Base-Modification mRNA Editing Through Deamination – the Good, the Bad and the Unregulated," TIG 12(10):418-424.	
	5	Verweij, (1999) "Rational Design of New Tumoractivated™ Cytotoxic Agents," Oncology 57(1):9-15.	
	6	NCBI Accession No. AC002369.	
	7	NCBI Accession No. AL078593.	
	8	NCBI Accession No. G38167.	
	U	Amino Acid and Nucleic Acid Sequence Match Database Sheets, Document WO/9902546 (January 21, 1999)	
	U	Nucleic acid and Amino Acid Database Sheets, Accession Number A1435527, April 13, 1999	

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	U	Kappel et al, Regulating Gene Expression in Transgenic Animals, Current Opinion in Biotechnology 3: 548-553, 1992.	
	U	Mullins and Mullins., Perspective Series: Molecular Medicine in Genetically Engineered Animals, J. Clin. Invest. 98(11): S37-S40, 1996.	
	U	Mullins et al., Fulminant Hypertension in Transgenic Rats Harboring the Mouse Ren-2 Gene. Nature 344: 541-544, April 5, 1990	
	V	Houdebine, Production of Pharmaceutical Proteins from Transgenic Animals. Journal of Biotechnology 34:269-287, 1994.	
	V	Rieger et al., Glossary of Genetics and Cytogenetics: Classical and Molecular, Fourth Completely Revised Edition, Springer-Verlag, New York, pages 17 and 18, 1976.	
	V	Taurog et al., HL-B27 in Inbred and Non-Inbred Transgenic Mice. The Journal of Immunology 141(11): 4020-4023, December 1, 1988.	
	V	Mullins and Mullins, Transgenesis in Nonmurine Species, Hypertension 22: 630-633, 1993	
	W	Wall, R.J., Transgenic Livestock: Progress and Prospects for the Future. Theriogenology 45: 57-68, 1996	
	W	Lazar et al., Transforming Growth Factor Alpha: Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities, Molecular and Cellular Biology 8(3): 1247-1252, March 1988.	

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	W	Mullins, et al., Expression of the DBA/2J Ren-2 Gene in the Adrenal Gland of Transgenic Mice. The EMBO Journal 8(13): 4065-4072, 1989.	
	W	Niemann, H., Transgenic Farm Animals get off the Ground. Transgenic Research 7: 73-75, 1998.	
	X	Overbeek, Paul A., Transgenic Phenomenology Within Transgenic Animal Technology, A Laboratory Handbook Edited by Carl A. Pinkert, 1994.	
	X	Hammer, et al., Spontaneous Inflammatory Disease in Transgenic Rats Expressing HLA-B27 and Human Beta(2)Microglobulin: An Animal Model of HLA-B27-Associated Human Disorders. Cell 63:1099-1112, November 30, 1990.	
	X	Niemann, H., Transgenic Farm Animals Get off the Ground. Transgenic Research 7: 73-75, 1998	
	X	Cameron, Ewan R., Recent Advances in Transgenic Technology. Molecular Biotechnology 7: 253-265, 1997	
	14	Somasekaram, A., et al., "Intracellular Localization of Human Cytidine Deaminase, Identification of a Functional Nuclear Localization Signal," The Journal of Biological Chemistry, 1999, pp. 28405-28412, Vol. 274(40).	
	15	Weiner, K., et al., "Primary Structure of Human Deoxycytidylate Deaminase and Overexpression of its Functional Protein in Escherichia coli," The Journal of Biological Chemistry, 1993, pp. 12983-12989, Vol. 268(17).	
	16	EMBL Database Report for Accession No. AL138875, February 5, 2000 (XP-002186947)	

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PTO/SB/08B (10-96)

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<div style="text-align: center;">Substitute for form 1449B/PTO</div> <div style="text-align: center; font-size: 1.2em; font-weight: bold; margin-top: 10px;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</div> <div style="text-align: center; font-size: 0.8em; margin-top: 10px;">(use as many sheets as necessary)</div>		<div style="text-align: center; font-weight: bold; margin-bottom: 5px;">Complete if Known</div> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Application Number</td><td style="width: 50%;">N/A</td></tr><tr><td>Filing Date</td><td>February 24, 2004</td></tr><tr><td>First Named Inventor</td><td>Rachel E. Meyers, et al.</td></tr><tr><td>Group Art Unit</td><td>N/A</td></tr><tr><td>Examiner Name</td><td>N/A</td></tr><tr><td>Attorney Docket Number</td><td>MPI00-022PIRDV1M</td></tr></table>		Application Number	N/A	Filing Date	February 24, 2004	First Named Inventor	Rachel E. Meyers, et al.	Group Art Unit	N/A	Examiner Name	N/A	Attorney Docket Number	MPI00-022PIRDV1M
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Sheet	4	of	4												

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	17	EMBL Database Report for Accession No. AI435527, March 16, 1999 (XP-002186948)	
	18	EMBL Database Report for Accession No. AI767392, June 30, 1999 (XP-002186949)	
	19	EMBL Database Report for Accession No. AWO73866, October 18, 1999 (XP-002186950)	
	20	EMBL Database Report for Accession No. AI142574, September 28, 1998 (XP-002186951)	
	21	EMBL Database Report for Accession No. BF114724, October 26, 2000 (XP-002186952)	
	22	EMBL Database Report for Accession No. Q9WYN5, November 12, 1999 (XP-002186953)	
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		Filing Date	February 24, 2004		
		First Named Inventor	Rachel E. Meyers, et al.		
		Group Art Unit	N/A		
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Sheet	1	of	1		

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	U.S. Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document (MM-DD-YYYY)	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² <i>(if known)</i>				
	9	US 5,622,851			Maley, F. et al.	04-22-1997	

FOREIGN PATENT DOCUMENTS								
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		Office ³	Number ⁴	Kind Code ⁵ <i>(if known)</i>				
	10	WO	97/05254	A1	Centre de Recherche de L-Hopital	02-13-1997		
	11	WO	98/45472	A1	Harosh, I.	10-15-1998		
	12	WO	99/02546	A1	Human Genome Sciences, Inc	01-21-1999		
	13	EP	1,033,401	A2	Genset	09-06-2000		

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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

- I. The information disclosure statement submitted herewith is being filed:
☒ Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

OR

☐ *After* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

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Sean Hunziker

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Practitioner's Docket No. MPI00-022P1RDV1M

- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.

☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

FEE PAYMENT

2. ☐ The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

☒ Applicant believes no fee is due in connection with this submission.

Fee due \$0.00

METHOD OF PAYMENT OF FEE

3. ☐ Attached is a check in the amount of \$ _____ .
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☐ A duplicate of this request is attached.

If any additional fees are due, please charge Account 501668.

February 24, 2004

MILLENNIUM PHARMACEUTICALS, INC.

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